

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/09 has been entered.

2. Applicant's arguments filed 11/17/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 40-50 are newly added and are pending in this office action. Claims 26-39 are cancelled.

5. Because claims 26-39 are cancelled, the rejections under 35 U.S.C 102 (b) by Keller (US 5,129,824) and 103(a) over Keller (US 5,129,824) in view of Hill (US 5,993,784) and Aberg et al. (US 5,807,541) are moot.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller (US 5,129,824) in view of Hill (US 5,993,784) and Aberg et al. (US 5,807,541).

Keller teaches a self-treatment method of treating gingival comprising: physically removing biofilm from the tooth surface (i.e., supra gingival) with a tooth brush (see abstract, as required by item 40a, which reasonably include toothpaste with soft abrasives), which also reasonably removes biofilm from the interproximal tooth surface (between the teeth) (as required by item 40b, see abstract and col. 3, lines 4-5 and 9-10). Intrinsically a toothbrush includes three to five ribs and grooves (as required by instant claims 41-42). Keller further teaches that brushing may also include the use of interdental tooth brush (i.e., proxy brush, see col. 3, lines 14-15), in which intrinsically the proxy brush will include three to five ribs and grooves (as required by instant claims 43-44). Keller also teaches that dental floss is employed to remove biofilm from subgingival surfaces (as required by item 40c) wherein the gingival detachment is about 3mm (see col. 7, lines 45-47). Keller further teaches the use of dental floss for applying medicament to the infected site (see col. 5, lines 1-14) which intrinsically will remove biofilm from the tooth surface because Keller teaches “the teeth are flossed in the usual manner” or “brushed” and thus will remove biofilm/plaque/food particles on the tooth. It should be noted that all tooth brushes comprise of ribs and grooves (as required by instant claim 40a)

Additionally Keller teaches the use of gel (i.e., proxy gel/tooth paste intrinsically comprises soft abrasives; as required by instant claim 46; see abstract and col. 3, lines 23-25) wherein reasonably the gel contains soft abrasives for brushing the teeth. Keller also teaches that the self treatment may be carried/applied every 8-12 hours (i.e., at least once every 24 hours; as it relates to claims 48-49). Thus if applied every 8 hours

Art Unit: 1618

will equate to twice every twenty four hours (see col. 7, lines 27-30, as it relates to claim 49).

Although Keller teaches other medicaments may be employed (see abstract and col. 7, lines 10-12), Keller however fails to teach that the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes and also fails to teach the use of therapeutic agents such as NSAIDs (i.e., as it relates to claims 45-47) and is silent as to the method steps carried out after eating as required by instant claim 50).

Hill and Aberg are added to remedy the deficiencies in Keller.

Hill teaches low foaming toothpaste with soft abrasives that is employed with a ribbed and grooved bristled tooth brush (as required by instant claim 40a), wherein the toothbrush includes 3-5 ribs and grooves (as it relates to claims 41-42; see abstract, Figs 1-4b and col. 6, lines 47 and 58 for the abrasives) and wherein the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes, (see col. 7, lines 45-47 and col. 11, line 33, as required by instant claim 40 a,b and c). Because toothpaste would be used on a toothbrush, it would be obvious that brushing of the supragingival occurs.

However, Hill fails to teach use of specific therapeutic agents such as NSAIDs and dental floss.

Aberg et al teach reducing dental caries/cavities by administering toothpaste with a medicament such as NSAIDs for treating periodontal disease, (see abstract and col. 6, lines 49-58; as required by instant claims 45-46).

However Aberg fails to teach using ribbed and grooved bristled tooth brushes.

One of ordinary skill in the art would have been motivated to expand the teaching of Keller to remove biofilm removal with a tooth brush, proxy brush and floss by substituting the tooth brush of Keller with Hill's, since Hill specifically teach use of ribbed grooved bristle tooth brushes to brush the supragingival tooth surface of the tooth, wherein it is well known that brushing with toothpaste removes biofilm. Employing the toothbrush and the soft abrasive toothpaste of Hill will intrinsically result in the abrasives physically being worked into the supra and subgingival pockets of the patients mouth suffering from periodontal disease. It is well known in the art that brushing and flossing are used everyday for the removal of plaque/biofilm and or food particles on the teeth.

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Keller and Hill with Aberg et al and add a NSAID to the toothpaste or dental floss for the treatment of periodontal disease because Aberg teaches periodontal disease relates to a condition in which the gingival and the alveolar bone become detached if periodontal disease is not treated, and the bacteria that causes the periodontal disease can gain access to the blood stream and cause vascular disease. Therefore, one of ordinary skill in the art would have been motivated to add Aberg's NSAID to toothpaste for brushing or add NSAID to dental floss for flossing to remove biofilm in pockets of the tooth of the patient suffering from periodontal disease because Keller teaches that therapeutic agents may be added to such formulation with a reasonable expectation of success.

Also because Keller teaches that self-treatment may be carried out twice every 24 hours or between 8-12 hours, based on the severity of the gingival treatment, the

Art Unit: 1618

frequency of twice every twenty four hours meets the limitation of "at least once every twenty four hours". It is well known in the art to floss or brush your teeth after meals, thus a patient with a gingival detachment would be inclined to brush or floss his/her teeth after every meal to prevent food particles entering the gingival pocket in order to minimize decay that may prolong treatment.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
1/4/10

/Robert C. Hayes/
Primary Examiner, Art Unit 1649